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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

VALEANT PHARMACEUTICALS
INTERNATIONAL, INC.; SALIX
PHARMACEUTICALS, INC.; PROGENICS
PHARMACEUTICALS, INC.; and WYETH
LLC, formerly known as WYETH,

Plaintiffs,

v.

ACTAVIS LABORATORIES FL, INC.;
ACTAVIS LLC; TEVA
PHARMACEUTICALS USA, INC.;
and TEVA PHARMACEUTICALS
INDUSTRIES LTD.,

Defendants.

Civil Action No.: _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Valeant Pharmaceuticals International, Inc. (“Valeant”), Salix Pharmaceuticals, Inc. (“Salix”), Progenics Pharmaceuticals, Inc. (“Progenics”), and Wyeth LLC (collectively “Plaintiffs”) by way of Complaint against Defendants Actavis Laboratories FL, Inc. (“Actavis FL”), Actavis LLC, Teva Pharmaceuticals USA, Inc. (“Teva USA”), and Teva Pharmaceuticals Industries Ltd. (“Teva Ltd.”) (collectively “Actavis” or “Defendants”), allege as follows:

THE PARTIES

1. Plaintiff Valeant is a corporation organized and existing under the laws of Canada. Its United States headquarters are located at 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.

2. Plaintiff Salix is a corporation organized and existing under the laws of California, having its principal place of business at 8510 Colonnade Center Drive, Raleigh, NC 27615. Salix is the registered holder of approved New Drug Application No. 208271, which covers Relistor[®] tablets.

3. Plaintiff Progenics is a corporation organized and existing under the laws of Delaware, having its principal place of business at One World Trade Center, 47th Floor, New York, NY 10007.

4. Plaintiff Wyeth LLC, formerly Wyeth, is a Delaware LLC, having places of business at 235 East 42nd Street, New York, NY 10017, and One Giralda Farms, Madison, NJ 07940.

5. Upon information and belief, Defendant Actavis FL is a corporation organized and existing under the laws of Florida, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey.

6. Upon information and belief, Defendant Actavis LLC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey.

7. Upon information and belief, Defendant Teva USA is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1090 Horsham Road, North Wales, PA 19454.

8. Upon information and belief, Defendant Teva Ltd. is a publicly-traded company organized and existing under the laws of Israel, having its corporate headquarters at 5 Basel

Street, P.O. Box 3190, Petach Tikva 4951033, Israel.

9. Upon information and belief, Actavis FL and Actavis LLC are wholly-owned subsidiaries of Teva USA, which is a wholly-owned subsidiary of Teva Ltd.

NATURE OF THE ACTION

10. This is an action for infringement of United States Patent Nos. 8,420,663 (“the ’663 patent”); 8,524,276 (“the ’276 patent”); 8,956,651 (“the ’651 patent”); 9,180,125 (“the ’125 patent”); and 9,314,461 (“the ’461 patent”) arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Actavis’s filing of an Abbreviated New Drug Application (“ANDA”) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to market its generic methylnaltrexone bromide tablets, 150 mg (“Actavis’s generic methylnaltrexone bromide tablets”).

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

12. Upon information and belief, this court has jurisdiction over Actavis FL. Upon information and belief, Actavis FL is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Actavis FL directly, or indirectly, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Actavis’s generic methylnaltrexone bromide tablets. Upon information and belief, Actavis FL’s principal place of business is at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey. Upon information and belief, Actavis FL has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court

by asserting counterclaims in other civil actions initiated in this jurisdiction.

13. Upon information and belief, this court has jurisdiction over Actavis LLC. Upon information and belief, Actavis LLC is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Actavis LLC directly, or indirectly, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Actavis's generic methylnaltrexone bromide tablets. Upon information and belief, Actavis LLC's principal place of business is at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey. Upon information and belief, Actavis LLC is registered to do business in New Jersey and purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Actavis LLC has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

14. Upon information and belief, this Court has jurisdiction over Teva USA. Upon information and belief, Teva USA is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Teva USA directly, or indirectly, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district, and this judicial district is the likely destination of Teva USA's generic products. Upon information and belief, Teva USA operates and maintains branches in Fairfield, New Jersey; Woodcliff, New Jersey; and Fairfield New Jersey. Upon information and belief, Teva USA is registered in the State of New Jersey as a "wholesaler" and "manufacturer and wholesales" of drugs, with Registration Nos. 5003436 and 5000583. Upon information and belief, Teva USA has previously submitted to the jurisdiction

of this Court and has further previously availed itself of this Court by filing actions in this jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction.

15. Upon information and belief, this Court has jurisdiction over Teva Ltd. Upon information and belief, Teva Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Teva Ltd. intentionally markets and provides its generic pharmaceutical products to residents of this State, enjoys substantial income from this State, and maintains a physical presence within this State at least through its wholly-owned subsidiary Teva USA. Upon information and belief, Teva Ltd. has further previously availed itself of this Court by filing actions in this jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction.

16. Upon information and belief, Actavis FL, Actavis LLC, Teva USA and Teva Ltd. hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling and distributing generic products in the United States. Upon information and belief, Actavis Laboratories FL, Inc., Actavis LLC, Teva USA, and Teva Ltd. operate as a single integrated business.

17. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

THE PATENTS IN SUIT

18. The U.S. Patent and Trademark Office (“PTO”) issued the ’663 patent on April 16, 2013. The ’663 patent claims, *inter alia*, methods of using compositions of methylnaltrexone. Plaintiffs hold all substantial rights in the ’663 patent and have the right to sue for infringement thereof. A copy of the ’663 patent is attached hereto as Exhibit A.

19. The PTO issued the '276 patent on September 3, 2013. The '276 patent claims, *inter alia*, compositions of methylnaltrexone for oral administration. Plaintiffs hold all substantial rights in the '276 patent and have the right to sue for infringement thereof. A copy of the '276 patent is attached hereto as Exhibit B.

20. The PTO issued the '651 patent on February 17, 2015. The '651 patent claims, *inter alia*, compositions of methylnaltrexone for oral administration. Plaintiffs hold all substantial rights in the '651 patent and have the right to sue for infringement thereof. A copy of the '651 patent is attached hereto as Exhibit C.

21. The PTO issued the '125 patent on November 10, 2015. The '125 patent claims, *inter alia*, compositions of methylnaltrexone and methods of using the same. Plaintiffs hold all substantial rights in the '125 patent and have the right to sue for infringement thereof. A copy of the '125 patent is attached hereto as Exhibit D.

22. The PTO issued the '461 patent on April 19, 2016. The '461 patent claims, *inter alia*, compositions of methylnaltrexone for oral administration. Plaintiffs hold all substantial rights in the '461 patent and have the right to sue for infringement thereof. A copy of the '461 patent is attached hereto as Exhibit E.

23. Salix is the holder of New Drug Application ("NDA") No. 208271 for Relistor[®] tablets. In conjunction with NDA No. 208271, the '663 patent, '276 patent, '651 patent, '125 patent, and '461 patent are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

24. Methylnaltrexone bromide tablets, 150 mg, are sold in the United States under the trademark Relistor[®].

ACTAVIS'S INFRINGING ANDA SUBMISSION

25. Upon information and belief, Actavis filed or caused to be filed with the FDA ANDA No. 209615, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

26. Upon information and belief, Actavis's ANDA No. 209615 seeks FDA approval to sell in the United States Actavis's generic methylnaltrexone bromide tablets, intended to be a generic version of Relistor[®].

27. Valeant, Salix, Progenics, and Wyeth LLC received a letter from Actavis FL dated October 24, 2016, purporting to be a Notice of Certification for ANDA No. 209615 ("Actavis's notice letter") under Section 505(j)(2)(B)(iv) of the Act, 21 U.S.C. § 355(j)(2)(B), and 21 C.F.R. § 314.95(c). Actavis's notice letter was addressed to Progenics at New York, NY, Salix at Raleigh, NC, Valeant Pharmaceuticals North America LLC at Bridgewater, NJ, and Wyeth LLC at Madison, NJ, Wyeth Pharmaceuticals, Inc. at Collegeville, PA, and Pfizer, Inc. at Groton, CT and New York, NY.

28. Actavis's notice letter alleges that Actavis has submitted to the FDA ANDA No. 209615 seeking FDA approval to sell Actavis's generic methylnaltrexone bromide tablets, intended to be a generic version of Relistor[®].

29. Actavis's notice letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defense, provides no explanation of any non-infringement defense related to the '663 patent, '276 patent, '651 patent, '125 patent, or '461 patent.

30. Upon information and belief, ANDA No. 209615 seeks approval of Actavis's generic methylnaltrexone bromide tablets that is the same, or substantially the same, as Relistor[®].

31. Upon information and belief, Actavis FL's actions related to ANDA No. 209615 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of Actavis LLC, Teva USA, and Teva Ltd.

COUNT I AGAINST ACTAVIS

Infringement of the '663 Patent under § 271(e)(2)

32. Paragraphs 1-31 are incorporated herein as set forth above.

33. Under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '663 patent by submitting, or causing to be submitted to the FDA, ANDA No. 209615 seeking approval for the commercial marketing of Actavis's generic methylnaltrexone bromide tablets before the expiration date of the '663 patent.

34. Upon information and belief, Actavis's generic methylnaltrexone bromide tablets will, if approved and marketed, infringe at least one claim of the '663 patent.

35. Upon information and belief, Actavis will, through the manufacture, use, import, offer for sale, and/or sale of Actavis's generic methylnaltrexone tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '663 patent.

COUNT II AGAINST ACTAVIS

Declaratory Judgment of Infringement of the '663 Patent

36. Paragraphs 1-35 are incorporated herein as set forth above.

37. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

38. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

39. Actavis has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Actavis's generic methylnaltrexone bromide tablets before the expiration date of the '663 patent, including Actavis's filing of ANDA No. 209615.

40. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic methylnaltrexone bromide tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '663 patent.

41. Plaintiffs are entitled to declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic methylnaltrexone bromide tablets will constitute infringement of at least one claim of the '663 patent.

COUNT III AGAINST ACTAVIS

Infringement of the '276 Patent under § 271 (e)(2)

42. Paragraphs 1-41 are incorporated herein as set forth above.

43. Under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '276 patent by submitting, or causing to be submitted to the FDA, ANDA No. 209615 seeking approval for the commercial marketing of Actavis's generic methylnaltrexone bromide tablets before the expiration date of the '276 patent.

44. Upon information and belief, Actavis's generic methylnaltrexone bromide tablets will, if approved and marketed, infringe at least one claim of the '276 patent.

45. Upon information and belief, Actavis will, through the manufacture, use, import, offer for sale, and/or sale of Actavis's generic methylnaltrexone tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '276 patent.

COUNT IV AGAINST ACTAVIS

Declaratory Judgment of Infringement of the '276 Patent

46. Paragraphs 1-45 are incorporated herein as set forth above.

47. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

48. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

49. Actavis has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Actavis's generic methylnaltrexone bromide tablets before the expiration date of the '276 patent, including Actavis's filing of ANDA No. 209615.

50. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic methylnaltrexone bromide tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '276 patent.

51. Plaintiffs are entitled to declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic methylnaltrexone bromide tablets will constitute infringement of at least one claim of the '276 patent.

COUNT V AGAINST ACTAVIS

Infringement of the '651 Patent under § 271(e)(2)

52. Paragraphs 1-51 are incorporated herein as set forth above.

53. Under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '651 patent by submitting, or causing to be submitted to the FDA, ANDA No. 209615 seeking approval for the commercial marketing of Actavis's generic methylnaltrexone bromide tablets before the

expiration of the '651 patent.

54. Upon information and belief, Actavis's generic methylnaltrexone bromide tablets will, if approved and marketed, infringe at least one claim of the '651 patent.

55. Upon information and belief, Actavis will, through the manufacture, use, import, offer for sale, and/or sale of Actavis's generic methylnaltrexone bromide tablets, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '651 patent.

COUNT VI AGAINST ACTAVIS

Declaratory Judgment of Infringement of the '651 Patent

56. Paragraphs 1-55 are incorporated herein as set forth above.

57. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

58. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

59. Actavis has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Actavis's generic methylnaltrexone bromide tablets before the expiration date of the '651 patent, including Actavis's filing of ANDA No. 209615.

60. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic methylnaltrexone bromide tablets will directly infringe and/or contributorily infringe at least one claim of the '651 patent.

61. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic methylnaltrexone bromide tablets will constitute infringement of at least one claim of the '651 patent.

COUNT VII AGAINST ACTAVIS

Infringement of the '125 Patent under § 271(e)(2)

62. Paragraphs 1-61 are incorporated herein as set forth above.

63. Under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '125 patent by submitting, or causing to be submitted to the FDA, ANDA No. 209615 seeking approval for the commercial marketing of Actavis's generic methylnaltrexone bromide tablets before the expiration of the '125 patent.

64. Upon information and belief, Actavis's generic methylnaltrexone bromide tablets will, if approved and marketed, infringe at least one claim of the '125 patent.

65. Upon information and belief, Actavis will, through the manufacture, use, import, offer for sale, and/or sale of Actavis's generic methylnaltrexone bromide tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '125 patent.

COUNT VIII AGAINST ACTAVIS

Declaratory Judgment of Infringement of the '125 Patent

66. Paragraphs 1-65 are incorporated herein as set forth above.

67. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

68. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory judgment relief consistent with Article III of the United States Constitution, and this case or controversy requires a declaration of rights by this Court.

69. Actavis had made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Actavis's generic methylnaltrexone bromide tablets before the expiration date of the '125 patent, including Actavis's filing of ANDA No. 209615.

70. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '125 patent.

71. Plaintiffs are entitled to a declaratory that future commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic methylnaltrexone bromide tablets will constitute infringement of at least one claim of the '125 patent.

COUNT IX AGAINST ACTAVIS

Infringement of the '461 Patent under § 271(e)(2)

72. Paragraphs 1-71 are incorporated herein as set forth above.

73. Under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '461 patent by submitting, or causing to be submitted to the FDA, ANDA No. 209615 seeking approval for the commercial marketing of Actavis's generic methylnaltrexone bromide tablets before the expiration of the '461 patent.

74. Upon information and belief, Actavis's generic methylnaltrexone bromide tablets will, if approved and marketed, infringe at least one claim of the '461 patent.

75. Upon information and belief, Actavis will, through the manufacture, use, import, offer for sale, and/or sale of Actavis's generic methylnaltrexone bromide tablets, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '461 patent.

COUNT X AGAINST ACTAVIS

Declaratory Judgment of Infringement of the '461 Patent

76. Paragraphs 1-75 are incorporated herein as set forth above.

77. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

78. There is an actual case or controversy such that the Court may entertain Plaintiffs'

request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

79. Actavis had made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Actavis's generic methylnaltrexone bromide tablets before the expiration of the '461 patent, including Actavis's filing of ANDA No. 209615.

80. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic methylnaltrexone bromide tablets will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '461 patent.

81. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic methylnaltrexone bromide tablets will constitute infringement of at least one claim of the '461 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Actavis on the patent infringement claims set forth above and respectfully request that this Court:

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '663 patent by submitting or causing to be submitted ANDA No. 209615 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Actavis's generic methylnaltrexone bromide tablets before the expiration of the '663 patent;

2. enter judgment that under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '276 patent by submitting or causing to be submitted ANDA No. 209615 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale,

and/or sale in the United States of Actavis's generic methylnaltrexone bromide tablets before the expiration of the '276 patent;

3. enter judgment that, under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '651 patent by submitting or causing to be submitted ANDA No. 209615 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Actavis's generic methylnaltrexone bromide tablets before the expiration of the '651 patent;

4. enter judgment that, under 35 U.S.C. § 271(e)(2), Actavis has infringe at least one claim of the '125 patent by submitting or causing to be submitted ANDA No. 209615 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Actavis's generic methylnaltrexone bromide tablets before the expiration of the '125 patent;

5. enter judgment that, under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '461 patent by submitting or causing to be submitted ANDA No. 209615 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Actavis's generic methylnaltrexone bromide tablets before the expiration of the '461 patent;

6. order that the effective date of any approval by the FDA of Actavis's generic methylnaltrexone bromide tablets be a date that is not earlier than the expiration of the '663 patent, '276 patent, '651 patent, '125 patent, and '461 patent or such later date as the Court may determine;

7. enjoin Actavis from the commercial manufacture, use, import, offer for sale, and/or sale of Actavis's generic methylnaltrexone bromide tablets until expiration of the '663

patent, '276 patent, '651 patent, '125 patent, and '461 patent or such later date as the Court may determine;

8. enjoin Actavis and all persons acting in concert with Actavis from seeking, obtaining, or maintaining approval of Actavis's ANDA No. 209615 until expiration of the '663 patent, '276 patent, '651 patent, '125 patent, and '461 patent;

9. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney's fees;

10. award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: December 6, 2016
Newark, New Jersey

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